



"Phederalism": The Regulation of Pharmacy Compounding and Two Years in the Regulatory Turf War Between Pharmacy and the Food and Drug Administration

Citation

"Phederalism": The Regulation of Pharmacy Compounding and Two Years in the Regulatory Turf War Between Pharmacy and the Food and Drug Administration (1998 Third Year Paper)

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8846813>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

Phederalism: The Regulation of Pharmacy Compounding and Two Years in
the Regulatory Turf War Between Pharmacy and the Food and Drug Adminis-
tration

Submitted by
Roger A. Fairfax
Harvard ID#50367053
Food and Drug Law
Professor Peter Barton Hutt
Winter Term 1998

Introduction

Pharmacy has long been considered among the most popular of professions, with pharmacists consistently topping surveys of whom Americans consider the most honest and ethical professionals.¹ Pharmacy is also one of the most regulated professions. The pharmacy profession has traditionally been regulated at the state level by legislatively-created state boards of pharmacy. These state agencies regulate all aspects of pharmacy practice, including admission to practice, standards of practice, and discipline of pharmacists. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy traditionally has been left to these state boards of pharmacy.

If pharmacy is well-respected and well-regulated, it is also well-represented. Pharmacy boasts hundreds of trade groups established to advocate the interests of pharmacists in state legislatures and Congress, to set standards for the profession, and to guard the profession from unwanted government regulation. While these pharmacy groups often operate in the state realm, where most pharmacy regulations are promulgated, sometimes an issue arises on the federal scene which would affect the practice

¹ *Pharmacists top honesty and ethics poll for 9th time* (visited Jan. 18, 1998) <<http://www.aphanet.org/APhA/lead/tophonesty.html>>; *7 in 10 Americans rate pharmacists highest in honesty and ethics* (visited Jan. 18, 1998) <<http://www.nacds.org/releases/release26.htm>>. Pharmacists topped the list of the most honest and ethical professionals for the ninth consecutive year. Pharmacists came in ahead of clergy (#2), physicians (#3), and college teachers (#4). Interestingly, lawyers only placed twentieth out of the 26 ranked professions, directly behind real estate agents. However, this lawyer—in-training takes some solace in the fact that lawyers still beat out both Houses of congress (#22 and #24), insurance salesmen (#25), and car salesmen (#26). See id.

of pharmacy nationwide. Recently, one such issue arose when, in the early 1990s, the practice of pharmacy compounding came under increased scrutiny by the Food and Drug Administration.²

Pharmacy compounding can be described as [t]he preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner, patient, pharmacist relationship in the course of professional practice, or for the purpose of or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing.³ Although most prescription drugs are received by pharmacies ready—to—dispense, compounding is practiced everyday by thousands of pharmacists, who are called upon by physicians to specifically tailor certain medications to the needs of individual patients.

Although [c]ompounding has always been a basic part of pharmacy practice,⁴ the art came under FDA scrutiny for several reasons. First, in the late 1980s, there were several well-publicized tragedies caused by incorrectly compounded medications. These incidents raised the awareness of consumer groups because the practice is largely used to prepare specialized medications for children and elderly patients. Also, the new FDA commissioner David Kessler took an aggressive stance towards pharmacy compounding, arguing that pharmacy compounding is essentially

²Although this paper focuses on the compounding of drugs for humans, there are many interesting issues arising from the compounding of drugs for animal use. See Symposium on compounding, 205 J. Amer. Veterinarian Medical Assn 189 (1994) (various articles discussing the impact of compounding practices and regulation on the practice of veterinarian medicine).

³*compounding Defined* (visited January 18, 1998) <<http://www.compassnet.com/iacp/aboutcompounding.htm>>.

⁴Lloyd V. Allen, Jr., compounding: A Professional Prerogative, 34 Amer. Pharmacy 4 (1994). See also Charles H. LaWall, Four Thousand Years of Pharmacy: An Outline History of Pharmacy and the Allied Sciences (1927).

small-scale manufacturing. Finally, the perception emerged that the usually vigilant state boards of pharmacy were surprisingly lax regarding regulation of the practice of pharmacy compounding.

As the FDA became increasingly aggressive in this area, pharmacy groups, which thought that pharmacy compounding should be regulated by the states, began an impressive legislative campaign to keep the FDA out of compounding regulation. By the mid-1990s, both the pharmacy profession and the FDA were aggressively lobbying Congress over the compounding issue, which came up as part of the FDA reform legislation put forth in the 104th Congress. When the smoke cleared this past November, the bipartisan Food and Drug Administration Modernization Act of 1997 had been passed. The events which took place in the time between the proposal and the passage of the Act's provisions affecting pharmacy compounding offers an interesting view of the role of interest groups in the legislative process, the rhetoric of federalism in the public debate, and the role of the FDA in protection of the public.

The first part of this paper examines the history of pharmacy compounding, an art that has been practiced, with varying significance, by pharmacists in America since the 17th century. The paper then explores the government regulation of compounding and the traditional role of the states and the federal government in this endeavor. Against that background, the paper examines the two-year legislative battle over the regulation of pharmacy compounding. After briefly examining the role of two trade associations that represented the interests of pharmacy on the

compounding issue and served as the catalyst for anti-FDA compounding legislation proposed in 1996, the paper details the path of the compounding bill through the legislative process in the 104th and 105th Congresses. Finally, the paper concludes by looking at the compounding provisions passed as part of the 1997 Act, and querying whether the FDA or pharmacy was the ultimate winner of the regulatory turf war over compounding.

History of Pharmacy Compounding

The nature of retail pharmaceutical practice and manufacturing has changed dramatically over the last century. While not as prominent today as it once was, compounding has been an integral part of the development of the retail pharmacy.⁶ Before the advent of mass-produced medicines, the pharmacist would compound several ingredients into a medicine pursuant to a formula contained in a prescription.⁷ Those who could master the art of compounding often became highly respected members of society as the knowledge and role of the pharmacist gave him a quite distinctive socio-professional standing.⁸

In fact, the compounding practices of 17th, 18th, and 19th century pharmacists served as the foundation for modern manufacturing practices. As one historian writes, from those who knew best the 'art and mystery of the apothecary' came many

⁵See George Edward Trease, *Pharmacy in History* (1964); Glenn Sonnedecker, *The*

Rise of Drug Manufacture in America, 21 *Emory Univ. Quarterly* 73 (1965).

⁶See George B. Griffenhagen, *The Pharmacy in History*, 29 *J. Int'l college of Surgeons* 789 (1958); Gregory J. Higby, *Evolution of Pharmacy*, in Alfonso R. Gennaro, ed., 8 *Remington's Pharmaceutical Sciences* 8-16 (18th ed. 1990).

⁷See *Science File*, L.A. TIMES, Nov. 6, 1997.

⁸Glenn Sonnedecker, *The Rise of Drug Manufacture in America*, 21 *Emory Univ. Quarterly* 73, 75 (1965).

original contributions upon which industrialization was to be based. ⁹

Although industrialization had begun to transform other allied health sciences in America by the 18th century, pharmacy remained the domain of the compounding pharmacist:

Already in the 17th century, and earlier, some individual substances used in medicine had been manufactured on a larger scale, but by neither intention, nor potential were they to replace the compounding of drugs behind the pharmacist's prescription counter ¹⁰

Even as late as the end of the 19th century, a review of state board of pharmacy statutory definitions of the practice of pharmacy reveals that compounding was considered the central task of pharmacists.¹¹

The twentieth century brought an increase in the number of mass-produced medicines, which caused a decline in the practice of pharmacy compounding. Before World War II, about 60 percent of all pharmaceutical dispensing was compounded.¹² However, during the post-war industrial boom, compounding suffered a sharp decline as pharmaceutical companies began manufacturing pre-fabricated medications on a wide scale. Such manufacturing practices relegated the pharmacist's role to that of primarily dispensing ready-made medications.

⁹Glenn Sonnedecker, *The Rise of Drug Manufacture in America*, 21 *Emory Univ. Quarterly* 73, 75 (1965).

¹⁰Glenn Sonnedecker, *The Rise of Drug Manufacture in America*, 21 *Emory Univ. Quarterly* 73, 75 (1965).

¹¹See George Howard Fall, *The Law of the Apothecary* 72 (1984). ¹²*Compounding Past Meets Pharmacy Future* (visited January 18, 1998) <<http://www.compassnet.com/~iacp/aboutcompounding.htm>>.

Today, the majority of drugs dispensed by pharmacists today arrive at the retail outlet in ready-to-take form.¹³ Purchased directly from wholesale distributors or from pharmaceutical companies directly, many of these drugs require little or no preparation.¹⁴ As one pediatrician noted, [p]harmacists today don't know how to compound medications. Most pharmacists today just do one thing – count pills before putting them in bottles.¹⁵ A pharmacist with a major chain drug store concurs: Most pharmacists today rarely are called upon to compound. Fewer than 3% of prescriptions filled in most large chain stores are compounded medications. 16

However, compounding activity has surged somewhat in recent years, as pharmacists are called upon to prepare such items as intravenous products, radiopharmaceuticals, chemotherapeutic agents, topical preparations, and suppositories.¹⁷ America's pharmacists today dispense approximately 43,000 compounded

¹³See Alfred Burger, *Drugs and People: Medications, Their History and Origins, and the Way They Act* 18 (1986).

¹⁴See Terence C. Green, *Licking, Sticking, counting, and Pouring — Is That All Pharmacists Do?*, 24 Creighton L. Rev. 1449 (1991).

¹⁵Interview with Dr. Johnye Ballenger, a pediatrician practicing in Watertown, MA (January 20, 1998). But, despite this characterization of pharmacy practice, pharmacists — even those who do not compound — carry tremendous responsibility (and potential liability) for the accuracy of the prescriptions they dispense. For some background on the liability of pharmacists for normal dispensing functions, see David B. Brushwood, *The Professional capabilities and Legal Responsibilities of Pharmacists: Should can Imply Ought?*, 44 Drake L. Rev. 439 (1996); Barry R. Furrow, *Enterprise Liability For Bad Outcomes From Drug Therapy: the Doctor, the Hospital, and the Drug Firm*, 44 Drake L. Rev. 377 (1996).

¹⁶Interview with a retail pharmacist with consumer Value Stores (c2VS), a large chain pharmacy that is headquartered in Woonsocket, RI (January 30, 1998).

¹⁷See Richard R. Abood & David B. Brushwood, *Pharmacy Practice and the Law* (1997); Bloom, *compounding in today's practice*, 31 American Pharmacy 31-37 (1991).

prescriptions daily.¹⁸ A pharmacist with an independent pharmacy says that an increased need for specialized medicines in recent years has largely fallen to independent and hospital pharmacies, where compounding is done more frequently.¹⁹

The nature of modern compounding has shifted from an emphasis on drug preparation from ingredients to alteration and manipulation of existing drug products. Pharmacy compounding is required for many reasons not immediately apparent to most patients. For example, pharmacists often compound medications that are highly unstable, preparing them in smaller amounts to safeguard patients from adverse effects.²⁰

Another popular function of compounding is tailoring medications for the individualized needs of patients. For instance, pharmacists may tailor medications for patients who are allergic to certain dyes or preservatives, or those patients who cannot tolerate the flavor or form of a particular medication.²¹ To a lesser extent, pharmacists may compound in order to provide physicians with the option to prescribe medications that may not be commercially available due to industry lag or market delay.²²

¹⁸*Compounded Past Meets Pharmacy Future* (visited January 18, 1998) <<http://www.compassnet.com/~iacp/aboutcompounding.htm>>. ¹⁹Interview with a retail pharmacist with an independent pharmacy, Skenderian Apothecary, in Cambridge, MA (February 1, 1998). The pharmacist estimates that 15% of prescriptions filled daily by the store are compound medications. ²⁰See *Compounded Past Meets Pharmacy Future* (visited January 18, 1998) <<http://www.compassnet.com/~iacp/aboutcompounding.htm>>.

²¹See *Compounding: The Need* (visited January 18, 1998) <<http://www.compassnet.com/~iacp/aboutcompounding.htm>>. ²²See *Compounding: The Need* (visited January 18, 1998) <<http://www.compassnet.com/~iacp/aboutcompounding.htm>>.

Government Regulation of Compounding

As one commentator recently noted, the field of pharmacy is no stranger to regulation.²³ But, although foreign governments have regulated the practice of pharmacy for many centuries,²⁴ American colonial governments did not begin to regulate the practice of pharmacy until the 1750s.²⁵ South Carolina and Virginia were the first colonies to pass legislation regulating the practice of pharmacy.²⁶ While crude and sometimes misdirected, these colonial laws regarding regulating pharmacy can be classed readily as America's first definite anti-quack legislation.²⁷

A half-century later, Louisiana became the first state to institute comprehensive pharmacy regulations.²⁸ By the late nineteenth century, the American Pharmaceutical Association had sponsored a model pharmacy law bill to guide state legislatures.²⁹

²³Gary G. Cacciatore, The Overregulation of Pharmacy Practice, 17 *Pharmacotherapy* 395, 395 (1997).

²⁴See R.G. Penn, The State Control of Medicines: The First 3000 Years, 8 *Brit. J. Clinical Pharmacology* 293 (1979). For an interesting analysis of drug regulation in Europe, see Graham Dukes, *The Effects of Drug Regulation* (1985).

²⁵See Lloyd G. Stevenson, Official Control of the Administration of Drugs: Historical Notes on Early Attempts at Regulation, 22 *Experimental Medicine and Surgery* 147 (1964).

²⁶See David L. Cowen, Colonial Laws Pertaining to Pharmacy, 23 *J. Amer. Pharmaceutical Assn.* 1236, 1239 (1934); Harold B. Gill, Jr., *The Apothecary in Colonial Virginia* (1972).

²⁷David L. Cowen, Colonial Laws Pertaining to Pharmacy, 23 *J. Amer. Pharmaceutical Assn.* 1236, 1239 (1934). Interestingly one of the first such statutes came about due to the fear of enslaved persons poisoning their captors in attempts at freedom. A 1751 South Carolina statute forbade apothecaries from hiring or training free or enslaved Blacks to work in their shops. See *id.* at 1237.

²⁸David L. Cowen, Louisiana, Pioneer in the Regulation of Pharmacy, 26 *Louisiana Historical Quarterly* 330, 330 (1943) (Louisiana's regulations were the earliest of the modern form of pharmaceutical regulation.) . Louisiana led the states into modern pharmacy regulation. Louisiana was the first state to separate medicine and pharmacy into two distinct disciplines. In addition, Louisiana was the first state to require examination and licensing of pharmacists. Louisiana also was the first state to establish a state board of pharmacy and to place restrictions on deteriorated drugs. See *id.*

²⁹Glenn Sonnedecker, Contribution of the Pharmaceutical Profession Toward Controlling the Quality of Drugs in the Nineteenth Century, in John B. Blake,

At the turn of the century, 39 states had adopted laws similar to this model pharmacy bill.³⁰ An early 20th century survey of state laws shows that states regulated and aggressively regulated pharmacy after the turn of the century.³¹

State Regulation

States have the authority to regulate the practice of pharmacy pursuant to their police powers under the Tenth Amendment.³² Regulation of pharmacy is usually achieved through state boards of pharmacy. A state board of pharmacy is typically an administrative agency charged with protecting the public health, safety, and welfare.³³

Typically, the boards are composed of practicing pharmacists, as well as consumer representatives and members of other health care professions.³⁴ State boards of pharmacy are responsible for the licensing of pharmacies and individual pharmacists, discipline of the same, and regulation of standards of practice.³⁵

ed., *Safeguarding the Public: Historical Aspects of Medicinal Drug Control* 106

(1970). See also James H. Beal, A General Form of Pharmacy Law Suitable for Enactment by the Several States of the United States, 48 *Proc. Amer. Pharm. Assn.* 309—18 (1900).

³⁰*Id*

³¹Robert P. Fischelis, A Survey of State Pharmacy Laws with Reference to the Sale of Drugs and Medicines by General Merchants, 20 *J. Amer. Pharmaceutical Assn.* 1331 (1931).

³²*See* U.S. Const. amend. X (The powers not delegated to the United States by

the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.); William Pettit, *Manual of*

Pharmaceutical Law 4 (1949).

³³Richard R. Abood and David B. Brushwood, *Pharmacy Practice and the Law* 212

(1997). For a description of the development of the role and function of state boards of pharmacy in the New England states, see George Howard Fall, *The Law of the Apothecary* 62-71 (1984).

³⁴Richard R. Abood and David B. Brushwood, *Pharmacy Practice and the Law* 212

(1997). See also William Pettit, *Manual of Pharmaceutical Law* 8-11 (1949).

³⁵Richard R. Abood and David B. Brushwood, *Pharmacy Practice and the Law* 212

(1997) at 213—225.

The activities of the various state boards of pharmacy are coordinated by the National Association of Boards of Pharmacy. The National Association of Boards of Pharmacy administers a standardized competency test for new pharmacy license applicants used by state boards of pharmacy.³⁶ In addition, the NABP proposes model legislation for use by state boards and oversees the transfer of licenses between states.³⁷

All of the fifty states have granted pharmacists the right to compound.³⁸ However, there is some disagreement as to the effectiveness of state regulation of compounding. Pharmacy industry advocates claim that compounding is pervasively regulated by the fifty states.³⁹ However, some observers have little faith in the ability or willingness of the states to effectively regulate pharmacy compounding. One observer argues that it is unlikely that state boards of pharmacy will stop the unsafe activities of compounding pharmacists.⁴⁰

Recent regulatory and legislative trends may demonstrate the states' lack of concern regarding the practice of compounding. For example, the Texas Board of Pharmacy recently modified rules to legalize potentially dangerous practices that had been used by

³⁶Id at 212.

³⁷Id.

³⁸*The Right and Responsibility of the Pharmacist to Compound* (visited January

18, 1998) <<http://www.compassnet.com/~iacp/aboutcompounding.htm>> (The right

— if not the obligation — to compound exists under the pharmacy laws of each of the fifty states. .

³⁹*The Right and Responsibility of the Pharmacist to Compound* (visited January

18, 1998) <<http://www.compassnet.com/~iacp/aboutcompounding.htm>>.

⁴⁰John H. Perrin, Unsafe Activities of Compounding Pharmacists, 52 *Amer. J.*

Health-System Pharmacy 2827, 2827 (1995).

10

pharmacists in the state.⁴¹ In addition, the Florida state legislature recently passed legislation allowing compounding pharmacists to copy manufactured medicines with ingredients of questionable quality.⁴² Although the governor of Florida subsequently vetoed the legislation, this episode demonstrates the sometimes permissive, attitude toward regulation of pharmacy compounding displayed by state boards of pharmacy.

This lack of regulation of compounding by the states is troubling because, while the practice of compounding is not as prominent as it once was, there is still reason to be concerned about the safety and standards of the practice. As the result of several well-publicized incidents where patients were injured or killed by incorrectly compounded medications, both the media and the Food and Drug Administration have become interested in the dangers of pharmacy compounding.⁴³ As one commentator has warned:

The profession seems to have forgotten that the preparation of safe and effective medication is not a trivial matter. Improper preparation can be deadly...Pharmacy will not remain America's most respected profession if pharmacy-prepared products continue to kill and injure.⁴⁴

Pharmacy analysts accuse both the pharmacy and medical industries of failing to deal with the problem because of the

⁴¹John H. Perrin, Unsafe Activities of Compounding Pharmacists, 52 Amer. J.

Health—System Pharmacy 2827, 2827 (1995).

⁴²John H. Perrin, Unsafe Activities of Compounding Pharmacists, 52 Amer. J.

Health—System Pharmacy 2827, 2827 (1995).

⁴³See Loyd V. Allen, Jr., Compounding: A Professional Prerogative, 34 Amer.

Pharmacy 4 (1994). See also Richard R. Abood and David B. Brushwood, Pharmacy

Practice and the Law 92 (1997).

⁴⁴Lawrence A. Trissel, Compounding Our Problems, 51 Amer. J. Hospital Pharmacy

1534, 1534 (1994).

11

profit involved in compounding.⁴⁵ It has been estimated that over 3,000 pharmacists are engaged in unsafe compounding activities.⁴⁶ Probably most alarming is the fact that, because of the need for alteration of existing medicines for consumption by children, more than 30,000 pediatricians regularly prescribe for their patients medications that require compounding of some form.⁴⁷ In addition, many elderly patients often require compounded medications of some form. ⁴⁸ Due to the combination of compounding tragedies in the news and heightened awareness on the part of the FDA, the issue of federal regulation of compounding was a hot-button political issue by the mid-1990s.⁴⁹

Federal Regulation

In regard to the 1906 Food and Drug Act, it has been argued that industry invited federal regulation – the emergence of an articulate consumer consensus, directed by science, made the food, beverage, and drug industries not only seek, but also plan for, federal legislation that regulated their industries.⁵⁰ In particular, the pharmaceutical industry welcomed with enthusiasm

⁴⁵John H. Perrin, *Pediatrician and Compounding Pharmacist: A Dangerous Liaison*, 150 *Archives of Pediatric and Adolescent Medicine* 224, 224 (1996) ([T]he driving motive is not the well-being of the patient but increased profit for the pharmacist and all too frequently for the pediatrician who may have a special business relationship with the compounding pharmacist.).

⁴⁶John H. Perrin, *Unsafe Activities of Compounding Pharmacists*, 52 *Amer. J. Health—System Pharmacy* 2827, 2827 (1995).

⁴⁷John H. Perrin, *Pediatrician and Compounding Pharmacist: A Dangerous Liaison*, 150 *Archives of Pediatric and Adolescent Medicine* 224, 224 (1996).

⁴⁸Interview with a retail pharmacist with an independent pharmacy, Skenderian

Apothecary, in Cambridge, MA (February 1, 1998).

⁴⁹John H. Perrin, *Unsafe Activities of Compounding Pharmacists*, 52 *Amer. J. Health—System Pharmacy* 2827, 2827 (1995).

⁵⁰Ilyse D. Barkan, *Industry Invites Regulation: The Passage of the Pure Food*

and Drug Act of 1906, 75 *Amer. J. Public Health* 18, 18 (1985).

the passage of the 1906 federal Food and Drugs Act, despite its broad definition of drug.⁵¹

While the federal government has closely regulated the development of drugs,⁵² regulation of the duties of retail pharmacist has largely been ignored by the FDA. Aside from occasional enforcement efforts directed at dispensing pharmacists designed to compel compliance with various drug regulations,⁵³ the FDA has largely avoided regulating the day-to-day functions of retail pharmacists:

The federal government sets no educational standards for pharmacists, does not operate colleges of pharmacy, does not license pharmacists, does not give them details as to how they should operate their stores. These matters are left largely to the state governments.⁵⁴

While federal regulation of prescription drugs certainly affects the pharmacist, regulation of the practice of compounding has largely been the province of the states.⁵⁵ Many of the Food, Drug & Cosmetic Act provisions dealing with adulteration or misbranding are meant to apply to drug manufacturers, not pharmacists. Only drug manufacturers, not pharmacists, are required, under the Act, to comply with current good

⁵¹James Harvey Young, *Pure Food: Securing the Federal Food and Drugs Act of 1906* 270 (1989).

⁵²See William M. Wardell and Louis Lasagna, *Regulation and Drug Development* (1975).

⁵³See Peter Temin, *Taking Your Medicine: Drug Regulation in the United States*

46—51 (1980).

⁵⁴William Pettit, *Manual of Pharmaceutical Law* 3 (1949).

⁵⁵It should be pointed out that pharmacies are subject to a whole host of federal regulations. See Richard R. Abood and David B. Brushwood, *Pharmacy Practice and the Law* 77-108 (1997). And, although routine FDA pharmacy inspections are rare, the Food, Drug & Cosmetic Act does empower FDA to inspect pharmacies without a warrant. See Section 704.

13

manufacturing practice, which entails registration with the FDA and possible inspection every two years.⁵⁶

However, a pharmacist, when compounding, performs virtually every act that a drug manufacturer performs, albeit on a much smaller scale.⁵⁷ Because of the dangers involved in pharmacy compounding, one might expect the Food and Drug Administration would assert an interest in regulating even these small scale manufacturing practices. Nonetheless, the Act, although not silent on the issue of compounding, provided a broad exemption for:

pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail. • •58

However, due to compounding tragedies in the late 1980s, the FDA suddenly adopted an aggressive posture with respect to pharmacies that it perceives are really manufacturing drugs, not practicing pharmacy.⁵⁹ To quell the fears of pharmacy groups that the FDA was intent on eliminating the right of pharmacists to compound medications as part of their ordinary practice,⁶⁰

⁵⁶See 21 U.S.C. S 351, 21 C.F.R. §§ 211.1—211.208 (1997).

⁵⁷James Robert Nielsen, Handbook of Federal Drug Law 14 (1992).

⁵⁸See 21 U.S.C. S 360(g) (1992).

⁵⁹James Robert Nielsen, Handbook of Federal Drug Law 14 (1992). See also Richard R. Abood and David B. Brushwood, Pharmacy Practice and the Law 92

(1997).

⁶⁰See Richard R. Abood and David B. Brushwood, Pharmacy Practice and the Law

92 (1997).

14

meetings were held to discuss the federal role in regulating pharmacy compounding. As a result, the FDA published the FDA 1992 Compliance Policy Guide, the purpose of which was to make clear that FDA was not planning to alter compounding pharmacists' exemption from registration as manufacturers under the Act.⁶¹ The Guide set out nine factors that would determine whether FDA would initiate enforcement proceedings against a pharmacy for manufacturing.⁶²

Even with this guidance, however, the boundaries of compounding in the regular course of retail pharmacy were difficult to establish. While it was clear that regular bulk compounding or advertising of compounded drug products would fall within the purview of FDA regulation, many compounding practices were not as easy to categorize.⁶³

As a result, the regular course of retail business exemption effectively exempted pharmacists from federal regulation of compounding. This left sole responsibility for the regulation of compounding in the hands of state legislatures and boards of pharmacy. But as one observer points out, much of what compounding pharmacists are doing today seems to be against federal laws and the laws of many states; however, ... no action from state boards of pharmacy can be expected.⁶⁴

⁶¹See *id.*

⁶²See *id.* at 93.

⁶³See ~ Cedars North Towers Pharmacy, Inc. v. United States, Food, Drug and Cosm. L. Rep. (CCH) 38,200 (S.D. Fla. 1978) (outlining a six-factor test for determining whether a pharmacist is exempt from registering as a manufacturer under the Act).

⁶⁴John H. Perrin, Pediatrician and Compounding Pharmacist: A Dangerous Liaison, 150 Archives of Pediatric and Adolescent Medicine 224, 225 (1996).

Two Years in the Life of a Bill: The Legislative Road to the FDA Modernization Act of 1997

It was against this background that the recent two-year battle over FDA regulation of compounding occurred. This encounter between aggressive and protective interest groups and the FDA illuminates many interesting issues surrounding the legislative and regulatory processes in the United States. Themes of federalism and protection of the public permeated the legislative process and public debate over the issue of the regulation of pharmacy compounding.

Three main sets of theories dominate the scholarly analysis of the American legislative process: 1) proceduralist theories, which emphasize the hurdles encountered by a bill on its way to becoming a law; 2) institutionalist theories, which emphasize the perspectives of the institutions responsible for enactment, implementation, and oversight of the ultimate statute; and 3) pluralist theories, which emphasize the role of lobbyists and interest groups affected by the proposed legislation.⁶⁵

All three of these theories are relevant to the story of the passage of the FDA Modernization Act of 1997, as Congress, the FDA, and pharmacy groups worked – sometimes together, sometimes at odds – toward a legislative resolution of the issue of pharmacy compounding regulation. The strategies displayed along the way by the Congress, interest groups, and the FDA offer an unique insight into the role of rhetoric of federalism and the goal of protection of the public in the legislative process.

⁶⁵See William N. Eskridge, Jr. and Philip P. Frickey, *Legislation: Statutes and the Creation of Public Policy* 1 (1995).

16

Pharmacy Trade Groups

The regulatory turf war was not initiated by FDA assertion of regulatory jurisdiction over pharmacy compounding, which has traditionally been the sole province of the states. Instead, the legislative fight was commenced by pharmacy groups seeking to ensure that the FDA would no longer have the power to infringe on pharmacists' right to compound. These interest groups, in asserting their position during the two-year legislative process, often argued that loyalty to American principles of federalism militated against the FDA entering the realm of regulation of pharmacy compounding.

The pharmacy profession is well-represented by a host of trade groups and associations. These groups, like most trade associations, have been extremely vocal and aggressive in advocating the interests of their profession in state legislatures and Congress. Two of these interest groups, the American Pharmaceutical Association and the International Association of Compounding Pharmacists, were at the forefront of the regulatory turf war over compounding in the FDA Modernization Act of 1997.

The American Pharmaceutical Association was founded in 1852, six years after the founding of the American Medical Association. The American pharmaceutical Association sets out to 1) advocate the interests of pharmacists; 2) influence the profession, government, and others in addressing vital pharmaceutical care issues; 3) promote the highest professional and ethical

standards; and 4) foster science and research in support of the practice of pharmacy.⁶⁶

The American Pharmaceutical Association has a long and successful track record of legislative advocacy. The Association played a major role in passing the federal Food and Drugs Act of 1906.⁶⁷ In addition, the American Pharmaceutical Association served as a catalyst for the system of state regulation of the pharmacy profession. In fact, most state statutes regulating the practice of pharmacies were based upon American Pharmaceutical Association models.⁶⁸

Where the American Pharmaceutical Association represents the interests of the entire pharmacy profession, the International Academy of Compounding Pharmacists represents a much narrower interest – that of the pharmacist regularly engaged in the practice of compounding. Formed six years ago, the International Association of Compounding Pharmacists is a non—profit association formed to increase awareness of the importance of compounding pharmacy in the health care system.⁶⁹ The group, which is based in Texas, has a Board of Directors composed of 29 registered pharmacists from across the nation.⁷⁰ The stated mission of the IACP is to:

⁶⁶ *Mission Statement of the American Pharmaceutical Association* (visited Jan.

18, 1998) <<http://www.aphanet.Org/APbA/abOut/m15ta.html>>.

⁶⁷ JH Beal, The American pharmaceutical Association as a Factor in American Food and Drug Legislation, 26 J. Amer. Pharmaceutical Assn. 747, 750 (1937). ⁶⁸ JH Heal, The American pharmaceutical Association as a Factor in American

Food and Drug Legislation, 26 J. Amer. Pharmaceutical Assn. 747, 750 (1937). ⁶⁹ *IACP Membership* (visited Jan. 18, 1998)

<<http://www.compassnet.com/—iacp/services.htm>>. ⁷⁰ *Board of Directors* (visited January 18, 1998) <<http://www.compassnet.com/—iacp/goals.htm>>.

[i]ncrease awareness of compounding pharmacy, globally, to a level of broad understanding, eliminating doubts of the validity of the practice and misunderstandings about the legalities of the practice. To elevate the professional compounding pharmacist to a position of credibility and respect among health care practitioners, whereas he or she will serve as the primary source of knowledge and expertise on drug treatment and modalities ⁷¹

The International Association of Compounding Pharmacists, like the American pharmaceutical Association, has an aggressive and organized legislative action component, which advocates the interests of compounding pharmacists in state legislatures and in Congress. This political action wing of the IACP, known as Compounders on Capitol Hill, meets for two days every June to further its legislative agenda for that year. The IACP describes its legislative retreat as an opportunity for pharmacists to educate Congress about the purpose, intent and necessity of compounding pharmacy. ⁷²

Instead of waiting for the FDA to pre-empt the states in the area of compounding regulation, the American Pharmaceutical Association and the International Association of Compounding Pharmacists led a host of pharmacy organizations in efforts to compel Congress to bar the FDA, once and for all, from regulating pharmacy compounding. In the process, these pharmacy groups sparked a regulatory turf war with the FDA that took two years to resolve.

⁷¹ *Mission Statement* (visited January 18, 1998) <<http://www.compassnet.com/-iacp/goals.htm>>. ⁷² *What is Compounders On Capitol Hill?* (visited January 18, 1998)

<[http://www.compassnet.com/-iacp/compounders_on capitol hill.htm](http://www.compassnet.com/-iacp/compounders_on_capitol_hill.htm)>.

Compounding Legislation Efforts in the 104th Congress

In early 1996, a pharmacy profession periodical opined that protecting pharmacists' right to compound from incursions by the Food & Drug Administration should be a slam dunk in the antiregulatory, anti-FDA mode that House Republicans are in, from Speaker Newt Gingrich on down.⁷³ But as pharmacy groups would later discover, the legislative road ahead would be anything but a slam dunk.

However, in early 1996, pharmacy groups were justifiably optimistic about the prospects for passage of the anti-FDA reform package.⁷⁴ More than 120 members of the House had endorsed free standing provisions prohibiting FDA from regulating pharmacy compounding.⁷⁵ The proposed legislation was bipartisan – the three main sponsors of the anti-FDA legislation were Rep. Bill Brewster, a Democrat from Oklahoma, and Rep. Jack Fields, a Republican from Texas, and Rep. Tom DeLay, a Republican from Texas.⁷⁶

What made things even more promising for the legislation was the fact that two of the three main sponsors – Brewster and Fields – did not plan to run for re-election in November of 1996. This insulated the bill's lead proponents from fundraising

⁷³Michael F. Conlan, Congress working with an eye on election day, *Drug Topics*, January 8, 1996 at 84.

⁷⁴See Ronald M. Schwartz, Full Plate of Rx issues before Congress, *American Druggist*, February 1, 1996 at 16.

⁷⁵See *id.*

⁷⁶See Ronald M. Schwartz, Full Plate of Rx issues before Congress, *American Druggist*, February 1, 1996 at 16 (quoting an executive of the National Association of Retail Druggists as stating that 'strong bipartisan' support exists for Congress to defer compounding regulation to the states).

concerns and pressure from proponents of federal regulation of pharmacy compounding.⁷⁷

Furthermore, Representative Fields was a member of the influential House Commerce Committee, the committee where the legislation was to originate.⁷⁸ The credibility of the legislative campaign was also enhanced by the fact that Rep. Brewster was a registered pharmacist, the only R.Ph. in Congress.⁷⁹ In addition, Rep. Tom DeLay, a backbencher just two years prior, had ascended to the number three leadership position of House majority whip, which placed him in a strong position to translate into legislative action his views on the need for a sharp reduction in federal regulation.⁸⁰

The 1994 elections had delivered control of both houses of Congress to the Republicans, who were seen as allies of the pharmacy industry in reining in what it saw as an increasingly aggressive FDA in the area of pharmacy practice. As an industry weekly stated:

Pharmacists in every setting have an interest in [compounding], whether they practice the art or not. The Food & Drug Administration has been pursuing an enforcement policy in recent years that most of the profession believes usurps state regulatory authority and threatens traditional extemporaneous compounding.⁸¹

⁷⁷Michael F. Conlan, Congress working with an eye on election day, *Drug Topics*, January 8, 1996 at 84 (pointing out that some brand-name drug companies have prodded the FDA to keep a tight rein on compounding. There are concerns over high-volume compounders in effect manufacturing on a pharmacy license.).

⁷⁸See Official Congressional Directory, 104th Congress, 1995-1996 at 395.

⁷⁹See *id* at 218—19.

⁸⁰Michael F. Conlan, Power Politics: Presidential election year is here; combatants are ready, *Drug Topics*, January 8, 1996 at 80.

⁸¹*Id*

21

On the other hand, the FDA position was that compounding is subject to its jurisdiction and that certain compounding practices are in violation of the Food, Drug and Cosmetic Act.⁸² Although the FDA assured pharmacy groups that in its discretion it won't preclude extemporaneous compounding of reasonable quantities of drugs by pharmacists, such groups questioned the ambiguity of such promises.⁸³ In 1995, a coalition of pharmacy associations had thrown their full support behind H.R. 598, which it said was aimed at making it clear that the provisions of the Food, Drug and Cosmetic Act don't apply to licensed retail pharmacies that compound drugs in conformance with applicable local laws regulating the practice of pharmacy and medicine.⁸⁴

In April of 1996, a new bill, H.R. 3199, replaced H.R. 598.⁸⁵ H.R. 3199 was backed by Rep. Richard Burr, an influential Republican from North Carolina, and was co-sponsored by 42 other House members.⁸⁶ The legislation again provided that FDA regulations shall not apply to a drug that is compounded by a licensed pharmacist on the order of a licensed physician.⁸⁷

Although the bill had considerable support in the House, by May of 1996, it appeared that the sweeping nature of the rest of the FDA reform legislation connected to the compounding provision made it less likely that any related bills would easily make it

⁸²Rx Groups fight MedGuide, Chain Drug Review, March 11, 1996.

⁸³Rx Groups fight MedGuide, Chain Drug Review, March 11, 1996.

⁸⁴Id (statement of coalition of pharmacy groups supporting H.R. 598, the pharmacy compounding preservation bill); H.R. 598, 104th Congress, 1st Session (introduced January 20, 1995).

⁸⁵See House Reform Bill Shields Rx Compounding by Pharmacists, Drug Topics,

April 22, 1996.

⁸⁶See id.

⁸⁷H.R. 3199, 104th Congress, 2nd Session.

through both houses of Congress.⁸⁸ Opposition to the reform package began to pick up speed in the Senate, as Senator Edward Kennedy spoke out against the Senate version of the bill.⁸⁹ Furthermore, it was thought that, even if such wide-reaching legislation were to be passed by Congress, a presidential veto might be imminent.⁹⁰

In addition to hurdles and delays put in place by opponents of the more controversial elements of the FDA reform package, the compounding provisions were severely criticized by FDA commissioner David Kessler at a May 1996 agency reform hearing. Kessler called the proposed provisions barring FDA regulation of compounding one of the most glaring examples of a provision that undermines FDA'S authority to protect the public from unsafe and ineffective products.⁹¹ Kessler charged that exempting pharmacy compounding from FDA regulation essentially would encourage manufacturing under the guise of pharmacy compounding. 92 As a result, claimed Kessler, [a] shadow industry of unapproved generic drugs is likely to develop.⁹³ Kessler emphasized that lack of FDA regulation could adversely affect the health and safety of patients:

the exemptions would allow potentially dangerous compounding. For example, sterile drugs could be

⁸⁸See Michael Conlan, Final Act, Drug Topics, May 6, 1996.

⁸⁹See House Reform Bill Shields Rx Compounding by Pharmacists, Drug Topics, April 22, 1996 (quoting Senator Kennedy as vowing to campaign against sections

of the legislation he felt would cripple the FDA).

⁹⁰See *id.*

⁹¹Compounding protection bill could lead to patient deaths, Kessler charges, Drug Topics, May 20, 1996.

⁹²*Id.*

⁹³*Id.*

23

compounded (even on a large scale) without regard to current good manufacturing practices (CGMPs) for sterile products. Improperly compounded sterile products could result in serious adverse effects, including death.⁹⁴

A combination of growing opposition to the larger package and sharp criticism of the specific pharmacy provisions by Commissioner Kessler all but killed chances of passing compounding legislation before the August 1996 recess. Hopes of FDA reform legislation quickly faded as members of the 104th Congress turned their attention toward Chicago and San Diego for their party conventions.⁹⁵ By the 1996 election season, it was clear that, despite pharmacy groups spending almost \$350,000 on lobbying Congress in the first half of 1996, legislation that would have directed FDA to stay out of pharmacy compounding regulations failed. 96

Compounding Legislation Efforts in the 105th Congress

Despite the stalling of H.R. 598 in 1996, the prospects for the 105th Congress revisiting the issue in 1997 looked good as Republicans still controlled the House after the 1996 elections and most of the previous co-sponsors had been returned to office.⁹⁷ In addition, FDA Commissioner David Kessler had announced his resignation on November 25, 1996. Pharmacy groups seemed to

⁹⁴compounding protection bill could lead to patient deaths, Kessler charges, Drug Topics, May 20, 1996.

⁹⁵Michael F. Conlan, Clock is running down for Congress to pass FDA reform,

Drug Topics, August 5, 1996.

⁹⁶Michael F. Conlan, Rx firms spent big on lobbying in first half of '96, Drug Topics, November 18, 1996.

⁹⁷R.Ph.-backed bills to resurface in new Congress, Drug Topics, November 18,

1996. Although it was likely that the legislation would resurface in 1997, the issue lost one of its strongest supporters, Rep. Bill Brewster, the Democrat from Oklahoma who had sponsored the original compounding legislation,

and who had been the sole registered pharmacist in Congress. See id.

24

welcome the departure of the aggressive commissioner whose tenure at FDA, some believed, was marked by intrusions into practice areas regulated by the states.⁹⁸ One pharmacy group claimed that, under Kessler, the FDA had difficulty keeping its eye on a line between regulating pharmaceutical manufactures and not crossing over that line and stepping into regulating practice.⁹⁹ However, with Kessler gone, pharmacy groups hoped that the compounding legislation would regain the momentum it had nearly a year before.

The House compounding provision was introduced as an element of the FDA reform legislation in the House of Representatives in March of 1997.¹⁰⁰ Rep. Richard Burr and other sponsors of H.R. 1060 stated that the bi-partisan legislation provides that states, not FDA, have regulatory authority over pharmacy compounding.¹⁰¹ The bill had the full backing of the National Association of Boards of Pharmacy, the American Pharmaceutical Association, and the International Association of Compounding Pharmacists.¹⁰²

In addition to supporting the House legislation, pharmacy groups, in a brilliant strategic move, also focused on less controversial FDA legislation in the Senate. A critical stumbling block of the compounding legislation in the 104th Congress had been its attachment to controversial, sweeping FDA reform legislation. While the pharmacy groups did not necessarily favor

⁹⁸Michael F. Conlan, Kessler Era Ends, Drug Topics, December 9, 1996.

⁹⁹Michael F. Conlan, Kessler Era Ends, Drug Topics, December 9, 1996. ¹⁰⁰See H.R. 1060, 105th Congress, 1st Session (introduced March 13, 1997). ¹⁰¹Ronald M. Schwartz, A Burr under FDA's compounding saddle, American Druggist, June 1, 1997 (quoting letter from sponsors of H.R. 1060). ¹⁰²See Ronald M. Schwartz, A Burr under FDA's compounding saddle, American Druggist, June 1, 1997.

drastic reform of the FDA, pharmacy has viewed FDA reform legislation as a means to an end: use it as a vehicle. . .to get the agency to leave pharmacy compounding enforcement solely to the states. **103**

The connection between the politically charged issue of FDA regulatory overhaul and the compounding legislation unnecessarily harmed the latter as, [d]espite [its] importance to pharmacy, compounding. . .[is] among the least controversial elements of FDA reform measures.¹⁰⁴ Realizing this fact, pharmacy groups sought new host legislation in the beginning of 1997. The Senate bill for renewal of the 1992 Prescription Drug User Fee Act – a noncontroversial program designed to expedite reviews of new prescription drugs – was seen as the ideal vehicle for the compounding legislation that had stalled as a part of the broad FDA reform legislation of the 104th congress.¹⁰⁵

In June of 1997, Sen. Tim Hutchinson offered a pharmacy compounding provision in an amendment to S. 830, the Senate version of FDA reform legislation. Although the provision quickly cleared the Senate Labor & Human Resources Committee,¹⁰⁶ certain pharmacy groups were not enthusiastic about its efficacy in blocking FDA regulation of pharmacy compounding.¹⁰⁷ Particularly troubling for many pharmacy groups was a provision that would

¹⁰³Michael F. Conlan, Clock is running down for Congress to pass FDA reform, Drug Topics, August 5, 1996.

¹⁰⁴See Michael Conlan, Final Act, Drug Topics, May 6, 1996. ¹⁰⁵Compounding bill may be added to user fee act, Drug Topics, January 6, 1997.

¹⁰⁶See Senate panel limits compounding ads, Drug Topics, July 7, 1997 at 8.

¹⁰⁷See Senate plan to keep FDA out of compounding may not aid R.Ph.s, Drug Topics, August 4, 1997 (describing pharmacy groups' dissatisfaction with the medical need and non—advertising provisions of the Senate version of the bill).

require the prescribing physician or the pharmacist to cite a legitimate medical need for a compounded medication in order to be exempted from FDA jurisdiction.¹⁰⁸ The Senate provision also barred advertising of compounding services for particular drugs. Although the American Pharmaceutical Association and the International Association of Compounding Pharmacists had negotiated with Sen. Hutchinson and the FDA over the compounding provision, a coalition of smaller groups began to express dissatisfaction with the proposed statutory provision.¹⁰⁹

By early September 1997, it became clear that the House pharmacy compounding legislation was preferred by pharmacy groups.¹¹⁰ The House legislation was unequivocal in its opposition to federal regulation of pharmacy, providing that the federal Food, Drug, and Cosmetic Act shall not apply to a drug or device that is compounded by a pharmacist. . . . authorized by state law.' However, in the process of passing its the FDA reform bill, the House Commerce Committee subsequently dropped the pharmacy compounding provision from its FDA reform legislation in favor of working from the Senate language.²

By early October 1997, the pharmacy groups had split over the strategy in the wake of House abandonment of the compounding

¹⁰⁸See Compounding issue throwing kink in reform of FDA, Drug Topics, September 1, 1997.

¹⁰⁹See id.

¹¹⁰Compounding issue throwing kink in reform of FDA, Drug Topics, September 1, 1997 (The House FDA reform bill has compounding protections that all facets of pharmacy agree are preferable to the current Senate position. . . . 'See H.R. 1060, 105th Congress, 1st Session (1997); Ronald M. Schwartz, A Burr under FDA's compounding saddle, American Druggist, June 1, 1997. ²See S. Rept. 105-43; Congressional Quarterly, September 27, 1997 at 2310; Few Differences Remain in Move to Streamline FDA Process, Congressional Quarterly, October 11, 1997 at 2486; Compounding and FDA: An Issue not Settled, October 6, 1997 at 8.

legislation. The American Pharmaceutical Association argued for improvement of the Senate language, while the coalition of the other pharmacy groups thought it better to have the Senate compounding provision scrapped and start again fresh the following year.¹³ As the House and Senate conferenced the bill in late October, it was unclear whether the final statutory language would increase or decrease the FDA'S authority over pharmacy compounding

– or whether the Compounding provision would be included in the bill at all.⁴

As conferencing on the FDA reform bill wound down, it looked certain that compounding protection legislation was dead.¹⁵ Although Sen. Hutchinson had attempted to address the concerns of the pharmacy coalition regarding the Senate language, the House conferees refused to negotiate.⁶ In addition, a letter sent to the conference committee on behalf of pharmacy groups was unsuccessful in urging the modification of the medical need

³See Compounding and FDA: An Issue not Settled, October 6, 1997 at 8. Interestingly, the International Association of Compounding Pharmacists, while continuing to support the American Pharmaceutical Association in its efforts, concluded in early October that current FDA reform legislation relating to compounding, which is now in the Senate, is worse than current law and unless changes are made to clarify pharmacists' rights, this profession would be better without a compounding bill this year. *Legislative Memo*, October 21, 1997 (visited January 18, 1998) <http://www.compassnet.com/~iacp/memo_102197.htm>.

⁴See FDA compounding role still uncertain as reform bill moves ahead, *Drug Topics*, October 20, 1997 at 7.

¹⁵Michael F. Conlan, *Close Call*, *Drug Topics*, December 8, 1997 at 101.

⁶See *Few Differences Remain in Move to Streamline FDA Process*, *Congressional Quarterly*, October 11, 1997 at 2486 (The pharmacy industry, the FDA and members of Congress have long been attempting to force language acceptable to all.); Michael F. Conlan, *Close Call*, *Drug Topics*, December 8, 1997 at 101.

language in S.830.~ As a result, the pharmacy groups convinced Sen. Hutchinson to withdraw pharmacy compounding provisions from the bill.

However, in an abrupt shift, the House conferees capitulated, and the pharmacy compounding language was worked out at the eleventh hour.⁸ Just before adjourning in November of 1997, Congress cleared the conference report on the FDA reform legislation.⁹ The statement on the conference report accompanying the Food and Drug Administration Modernization & Accountability Act of 1997 (S.830) described the compounding provision as establish[ing] a rational framework for pharmacy compounding, which respects the State regulation of pharmacy while allowing an appropriate role for FDA.¹⁰ The Congressional Quarterly wrote that the legislation clarif[ies] that the FDA do not have jurisdiction over pharmacists who practice compounding.¹¹ The conference report itself stated that the bill would ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of

⁷See Letter from Pharmacy Coalition to Conference Committee (visited January 18, 1998) <http://www.compassnet.com/~iacp/conference_letter.htm>.

⁸See Republicans Close to Deal on Streamlining FDA, Congressional Quarterly, November 8, 1997.

⁹See Conference Report to Accompany S.830, The Food and Drug Administration Modernization and Accountability Act. (H. Rept. 105-399); FDA Conference Report Cleared by Congress, Health Legislation & Regulation, November 12, 1997.

¹⁰See Statement of Chairman James M. Jeffords on the Conference Report to Accompany S.830, The Food and Drug Administration Modernization and Accountability Act.

¹¹FDA Measure Looks Healthy After GOP Concessions, Congressional Quarterly, November 15, 1997 at 2852.

compounding.¹²² After a long legislative battle over FDA reform, Congress adjourned and S.830 was sent to the White House for the approval of the President.¹²³

On November 21, 1997, President Clinton signed into law S.830, the Food and Drug Administration Modernization Act of 1997.¹²⁴ In his signing statement, President Clinton characterized the legislation as the most comprehensive reform of our Nation's drug, medical device, and food laws in decades.¹²⁵ As to the compounding provisions, the President said the Act will also resolve the issue of pharmacy compounding. . .so that legitimate pharmacy compounding is allowed, while manufacture of unapproved drugs is not.¹²⁶

The Food and Drug Administration Modernization Act of 1997

The Act added a new Section 503A, Application of Federal Law to Practice of Pharmacy Compounding, to the Food, Drug and Cosmetic Act.¹²⁷ The Act makes clear that states have sole jurisdiction to regulate legitimate pharmacy compounding.¹²⁸ The Act provides that medical need is not necessary to allow a

¹²²See Conference Report to Accompany S.830, The Food and Drug Administration Modernization and Accountability Act. (H. Rept. 105-399); *Compounding*

Legislation: Preserving Patient Access to Compounded Drugs (visited 1/18/98) <http://www.compassnet.com/~iacp/press_releases.htm>.

¹²³See FDA Measure Looks Healthy After GOP Concessions, Congressional Quarterly, November 15, 1997 at 2852; Lori Nitschke, Compromise pact on revamping FDA rules heads to Clinton, The News & Observer, November 11, 1997 at A7.

¹²⁴See FDA Measure Signed by Clinton, Congressional Quarterly, November 22, 1997.

¹²⁵See Statement of President William J. Clinton, signing statement for S.830, the Food and Drug Administration Modernization Act of 1997.

¹²⁶See *id.*

¹²⁷See 21 U.S.C. § 353(a), 111 Stat. 2296, 2328 (1997). ¹²⁸See § 503A(a).

30

pharmacist to compound, a prescription is sufficient justification.²⁹ In addition, the Act makes clear that pharmacists may compound medications that are essentially copies of commercially existing products, provided the compounded medication produced a significant difference for an individual patient. Furthermore, missing from the law was the medical need provision that had been proposed in an earlier version and opposed by pharmacy groups.

Pharmacy groups triumphantly hailed the Act as a clear statement that states – not the FDA – regulate pharmacist compounding.³⁰ The American Pharmaceutical Association, which supported the retention and modification of the Senate compounding provision, claimed victory in the passage of the law:

This victory, capping more than three years of legislative commitment by APhA, was the result of a significant amount of work by APhA, the International Academy of Compounding Pharmacists (IACP), and a number of other pharmacy organizations.³¹

The American Pharmaceutical Association characterized the new law as a clear barrier to FDA regulation of pharmacy compounding. In describing the legislation, the Association asserted, [t]his package includes a provision clarifying that the FDA does not have jurisdiction to regulate the practice of pharmacist and physician compounding. •

²⁹Michael F. Conlan, Close Call, Drug Topics, December 8, 1997 at 101.

³⁰Id

³¹*compounding Legislation* (visited 1/18/98) <<http://www.aphanet.org/APhA/govt/legreg.html>>. ³²Id (emphasis in original).

31

The International Association of Compounding Pharmacists declaring that the Act was truly a victory for pharmacy, described the legislation as preserv[ing] a patient's access to important compounded drug therapies by recognizing the legality of pharmacy compounding practice. ~33

The National Community Pharmacists Association asserted the Act preserves the traditional right of pharmacists to compound medications with a physician's order and underscores the authority of the states, not the FDA, to continue to regulate the practice of pharmacy.³⁴ Despite the hurdles encountered during the two-year legislative battle, it seems that the pharmacy industry scored a tremendous legislative victory in the Food and Drug Modernization and Accountability Act.

Conclusion

In the 1997 FDA legislation, were principles of federalism vindicated at the expense of public safety? Does the new law compromise the FDA's ability to ensure drug safety? Probably not. It is not clear that the law represents a one-sided legislative victory. The FDA, during the extensive negotiations over the language of the Senate bill, was able to secure several significant provisions regulating practice of pharmacy compounding. Under the Act, compounding pharmacists are forbidden from advertising their services in regard to particular drugs.³⁵ Also, compounding pharmacists are forbidden from compounding a

¹³³ *Compounding Legislation: Preserving Patient Access to Compounded Drugs* (visited 1/18/98) <http://www.compassnet.com/~iacp/press_releases.htm>.

³⁴Michael F. Conlan, Close Call, Drug Topics, December 8, 1997 at 101. ³⁵See § 503A(a)(2)(B).

drug that has been removed from the market because of safety or effectiveness concerns.¹³⁶ Finally, although the Act allows compounding pharmacists to compound medicines that are essentially copies of products already commercially available, this practice may not take place on a regular basis.¹³⁷

However, it must be conceded that, despite these regulatory areas carved out by the FDA, the victory claimed by pharmacy groups is certainly more than symbolic. These groups were able to obtain a definitive statutory statement that states are the primary regulators of pharmacy compounding. In the process, themes of federalism and protection of the public arose as the pharmacy industry, FDA, and Congress all worked toward a resolution of the issue of pharmacy compounding regulation.

But while the pharmacy industry justifiably may claim victory, with the burdens already carried by FDA in regulating 25% of the American economy, it is probably for the best that the agency leave the regulation of compounding to the state boards of pharmacy. And, as a result of the exposure of the public to the issues during two-year legislative process leading up to the 1997 Act, state boards of pharmacy will likely feel added pressure from watchdog groups, the media, and state legislatures to provide effective monitoring of the practice of compounding by pharmacists licensed in their jurisdictions. Although federalism and autonomy were consistent issues throughout the regulatory turf war between pharmacy and the FDA, the public may yet be the ultimate victor.

¹³⁶See § 503A(b)(1)(C).

¹³⁷See § 503A(b)(1)(D).